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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,597	05/22/2000	John J. Voorhees	1718-009A	1700
7590 01/27/2005				
BRADLEY N. RUBEN 463 FIRST ST., SUITE 5A HOBOKEN, NJ 07030-1859		EXAMINER KIM, VICKIE Y		
		ART UNIT PAPER NUMBER		
		1614		

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/576,597	<b>Applicant(s)</b> VOORHEES ET AL.	
	<b>Examiner</b> Vickie Kim	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-24,31-39,41-45 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) 33-36,41-43 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24,31,32,37-39,44,45,48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Status of Application***

***RCE acknowledged***

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2004 has been entered.

The claims 22-24, 31-39, 41-45 and 48-50 are pending.

The previously elected claims 22-24, 31-32, 37-39, 44-45,48 and 50 ( see paper17) are presented for the examination.

The non-elected claims 33-36, 41-43 and 49 are maintained as withdrawn from the consideration.

***Response to Arguments***

1. Applicant's arguments with respect to claims 22-24, 31-39, 41-45 and 48-50 (before amended) have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment due to the scope changes necessitated the new ground(s) of rejection presented in this Office action.

***Claim Rejections - 35 USC § 102***

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2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 22-24, 31-32, 37-39, 44-45, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lanzendorfer et al**(US5952373) , **Burger** (US 5,665,367) or **Jokura et al**(JP 02193919, or English abstract) alone, or alternatively, unpatentably over any reference above in view of Broberg(1996, Integrin  $\alpha 2\beta 1$ -Dependent Contraction..), Murad(US5972999) and Kiyosuke et al(EP 742012).

The broadest independent claim 22 is drawn to a method of reducing scarring in acne-affected skin using a topical application of an MMP-1 inhibitor(e.g. genistein, quercetin).

Lanzendorfer et al(US'373, hereinafter) teaches a treatment or prophylactic treatment of acne skin conditions by administering genistein or quecetin, see column 5, lines 25-29 and claim 2. US'373 also teaches the combination of said active agent and

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other beneficial agents such as antibacterials(e.g. tetracycline, column 10, line 46), antioxidants(e.g.NAC(col.12, line 39), retinol(col.9, line 15), an inhibitor of cytochrome P-450 such as ketoconazole(col. 10, line 57-clo.13, line 15)) , see abstract and columns 9-13.

Burger(US'367, hereinafter) teaches acne treatment using quercetin as an active agent, see claim 6 and examples. US'367 further teaches an additional active agents beneficially included in the patented invention(e.g. retinoic acid, antioxidants(e.g. naringenin), antibacterials(e.g. ketoconazole, alcohols(ethanol) etc), see column 1, lines 12-60 ; column 4, line 52-63 and examples 7-8.

Jokura(JP'919, hereinafter) teaches acne treatment using genistein as an active agent(see abstract from CAPLUS database).

As evidenced by claim itself, the scarring is a manifestation of acne and a skin condition caused by acne. Thus, it is readily apparent to one of skilled artisan that preventing or reducing acne conditions would have resulted in reduction of the scarring.

Since US'373, US'367 or JP'919 teaches the use of genistein and quercetin in the prophylaxis or treatment of acne conditions, one would have envisaged the effective reduction of scarring in acne-affected skin by utilizing genistein or quercetin.

Thus, the claimed invention is not patentably distinct over the prior art of the record.

It is noted that the recitation(i.e. MMP-1 inhibitors) has not been given patentable weight because the recitation occurs in the preamble. In this case, the prior art teaches the genistein or quercetin. Therefore, MMP-1 inhibition is inherently met

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when application of genistein or quercetin is administered to reduce acne and consequently, to reduce the scarring as well. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted that the extrinsic evidence to support inherent feature(i.e. reduction of the scarring process, MMP-1 inhibition) is well documented in the publications, see PTO-891. For example, Broberg(1996, Integrin  $\alpha 2\beta 1$ -Dependent Contraction..) teaches that genistein is effective in scar formation(contraction) and also inhibits MMP-1 induction in keratinocytes and in skin fibroblasts, see page 32 at 3<sup>rd</sup> – 4<sup>th</sup> paragraphs and pages 33-34 at 1<sup>st</sup> paragraph, respectively. Murad(US5972999) and Kiyosuke et al(EP 742012) teach that quercetin is effective in the prevention and treatment of the scarring process; or modifying the thickness and elasticity of the skin via modulating collagenase(known as MMP-1 by skilled artisan, and also evidenced by applicant's own admission, see instant specification at page 4, lines 27) or elastase.

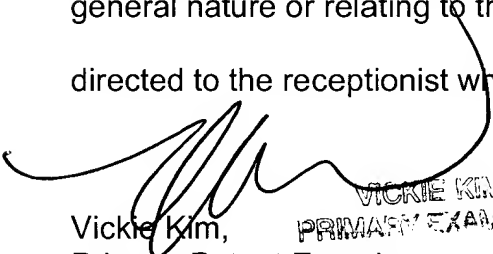
Thus, all the claimed subject matter is anticipated by **Lanzendorfer et al**(US5952373) , **Burger** (US 5,665,367) or **Jokura et al**(JP 02193919, or English abstract) alone, or alternatively, unpatentably over any reference above in view of

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Broberg(1996, Integrin  $\alpha 2\beta 1$ -Dependent Contraction..), Murad(US5972999) and Kiyosuke et al(EP 742012) .

**Conclusion**

4. No claim is allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Low Christopher can be reached on 571-272-0953. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

  
Vickie Kim,  
Primary Patent Examiner  
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VICKIE KIM  
PRIMARY EXAMINER